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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,143	04/21/2000	Ronald A. Schachar	PRES06-00163	6710

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EXAMINER

SHAY, DAVID M

ART UNIT PAPER NUMBER

3735

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/556,143

Applicant(s)

SCHACHAR

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on September 22, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 40-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

Applicant argues that March et al 'lacks any mention of using laser pulses "in a region of a ciliary body"' and thus the rejection is improper. The examiner cannot agree. The instant application defines the sclera in a region of the ciliary body as that part of the sclera about 1.5 millimeters posterior of the limbus (see the originally filed disclosure, the paragraph bridging pages 18 and 19), while the parent from which the instant case is purportedly a "continuation" defines such region as "the region of the sclera overlying the ciliary body" (see Schachar, U.S. Patent 6,197,056, column 3, lines 11-16). The method of March et al is directed towards penetrating the sclera to reach the level of Schlemm's canal, which will allow the outflow of aqueous and reduce intraocular pressure (See March et al, page 584, first paragraph). The internal mouth of the fistula of March et al is posterior to the cornea (see page 585, the caption to Figure 1) and the external scleral entry point of the fistula is posterior to the internal mouth of the fistula (see March et al, page 587, Figure 6). Given that the distance posterior to the cornea defined in the originally filed disclosure as "in the region of the ciliary body" is less than one tenth of an inch, and given that, according to the illustration in Figure 6 of March et al, the point of the fistula in the external sclera is on the level of the trabecular meshwork. This constitutes removal of a portion of the sclera in the region of the ciliary body" as claimed. This can be seen from the attached illustrations and text from Alder's Physiology of the Eye, which clearly shows the ciliary muscle attached to the margins of the trabecular meshwork (see Figure 6-6) and that the ciliary muscle forms that aspect of the eye that connects the trabecular meshwork to the iris and the iris to the sclera (see Figure 8-1 and page 232, third full paragraph to page 234, second full paragraph). Applicant also argues that March et al do not specifically mention that the purpose of the surgery is "to weaken the sclera of the eye" and "increase the working distance of

the ciliary muscle". The examiner acknowledges this lack of specific mention of these intended effects of the surgery of March et al. However, this does not preclude the production of such effects thereby.

Continuing, applicant asserts that the examiner has provided no fact or technical reasoning to support the determination of inherency. The examiner firstly notes, that the disclosures of the prior art are to be read in light of the knowledge of one of ordinary skill in the art. Given that one of ordinary skill in the art must at the very minimum be a ophthalmological surgeon, and therefore, have not only completed college with at least one course in physics and chemistry, but gone to a minimum of 3 years of medical school and interned for a period of time after that, one having ordinary skill must be recognized as being a highly educated surgeon. Given this level of education, the examiner respectfully submits that one of ordinary skill in the art would recognize that removing tissue from a structure such as the sclera must necessarily weaken the structure. The examiner is unaware of any process, material, or theory that affords or asserts the ability of strengthening a structure, or even allowing the structure to remain at the same strength, while removing some of the material that constitutes this structure. If applicant is aware of any such disclosure, the examiner would be most interested to review it. Absent any such showing, however, the examiner must rely upon the laws of physics as they are currently understood and presume that removal of the substance of a structure will leave that structure weaker than before the removal. Given that the structure is weaker, this necessarily requires that the structure will expand due to the internal pressure thereof in combination with it's weakened state. This expansion will also necessarily cause the effective working distance of the ciliary muscle to increase given that the ciliary muscle joins the iris to the sclera (see Figure 8-1 of

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Alders, cited above, since the sclera will expand due to the pressure in the eye pushing the now weakened (by the removal of tissue) sclera farther out. Thus the examiner must respectfully submit that one of ordinary skill in the art would immediately recognize that the intended results recited in the claim would, at least to a small degree, be produced by the procedure of March et al.

With regard to the double patenting rejections, applicant argues that because the parent cases have had restrictions in them, the double patenting rejections based on child cases cannot be maintained. The examiner respectfully notes that a double patenting rejection is improper only if the restricted out material corresponds to the currently claimed invention. It is not clear that this is the case, thus the examiner has maintained the rejections and will review the parent cases to determine the correlation between the material restricted out by the restrictions therein and the instantly claimed material.

The disclosure is objected to because the continuity information is inaccurate. The instant application does not contain the same disclosure as the parent application, U.S. Application Serial No. 09/032,830, and thus cannot properly be termed a continuation thereof. The specification should be amended to identify the instant application as a Continuation-in-part of this parent.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It is a copy of the oath submitted in the parent case, when the instant application is not a continuation of the parent case.

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention: the use of a laser. A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 54-59 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sand.

Sand teaches a method including providing a laser. The laser of Sand can be made operable to produce the claimed results by the appropriate adjustment of beam parameters and the application site.

Claims 40-59 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by March et al.

March et al teach removing scleral tissue by irradiating it with a laser to treat glaucoma. Stedman's Medical Dictionary defines ablate as "to remove"; abrade as "to wear away by mechanical action"; and incise as "to cut with a knife" since the laser produces no mechanical action per se and is not a knife per se, abrade will be construed to indicate wearing away by action of the light and incise will be construed to indicate cutting by action of the light. Since the laser burns through the sclera at the treatment site, there must be some tissue interposed the

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margin of the treatment site and the boundary beyond which the scleral tissue is not affected by the treatment wherein the collagen fibers are partially decomposed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-62 of U.S. Patent No. 5,489,299.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent application claims. Here, the patent application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific patent application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 45-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 5,529,076. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent application claims. Here, the patent application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific patent application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 45-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 5,465,737. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent application claims. Here, the patent application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific patent application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.



Claims 40-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 5,503,165. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent application claims. Here, the patent application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific patent application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Applicant's arguments filed September 22, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 45-59 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

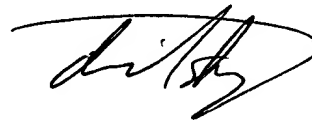
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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